

CLAIMS:

1. A method of making a composite material, the material comprising at least one amphiphilic component and at least one polymer component, the
5 method comprising the following steps:

providing a chemical system comprising the components of at least one polymer, at least one amphiphilic compound and a volatile solvent or solvent mixture, wherein

- 10 i) the polymer is a homopolymer, a random block copolymer or a mixture thereof;
ii) the amphiphilic compound has the ability to form a bilayer- or monolayer-containing phase; and

15 providing a phase diagram that graphically defines how the components of the chemical system interact in thermodynamically stable phases as a function of temperature, concentration and pressure,

removing the solvent(s) from the chemical system by shifting the
20 thermodynamic equilibrium point of said system in a direction based on the phase diagram, thereby obtaining the desired material.

2. The method as claimed in claim 1, wherein the step of removing solvent comprises solvent extraction against a liquid phase containing at least one
25 second solvent.

3. The method as claimed in claim 2, wherein the volatile solvent is not completely miscible with said second solvent.

30 4. The method as claimed in claim 2 or 3, wherein the second solvent is water, or lower cycloalkanes, preferably cyclohexane.

5. The method as claimed in any of claims 2 - 4, wherein the amphiphilic compound/polymer mixture is an emulsion, and the emulsion is injected into

an outer second solvent rich-phase, whereby particles are formed as a consequence of solvent removal.

6. The method as claimed in claim 1, wherein the step of removing solvent
5 comprises spraying the mixture, so as to evaporate the solvent.

7. The method as claimed in claim 1 or 2, wherein the composite material obtained is one of particles, solid implants, semi-solid, gel-like matrices, surface coatings.

10 8. The method as claimed in any preceding claim, wherein the bilayer-or monolayer-containing phase is cubic, sponge, lamellar, hexagonal, micellar or vesicular.

15 9. The method as claimed in any preceding claim, wherein the amphiphilic compound is selected from synthetic and natural polar lipids.

10. The method as claimed in any preceding claim, wherein the amphiphilic compound is anionic, cationic, zwitterionic or uncharged.

20 11. The method as claimed in any preceding claim, wherein the amphiphilic compound is selected from compounds having the ability to form a cubic, sponge, lamellar, hexagonal, micellar, or vesicular phase.

25 12. The method as claimed in any preceding claim, wherein the amphiphilic compound is an uncharged monoglyceride, preferably glycerylmonooleate.

13. The method as claimed in any preceding claim, wherein the amphiphilic compound is selected from monoelaidin, phosphatidyl-ethanolamine, phospholipids and PEGylated phospholipids.

30 14. The method as claimed in any preceding claim, wherein the polymer is partially or completely soluble in organic solvents but not completely soluble in the second solvent.

15. The method as claimed in any preceding claim, wherein the polymer is a homopolymer selected from poly(lactide), poly(glycolide), poly(p-dioxanone), poly(caprolactone), polyhydroxyalkanoate, polypropylene fumarate, polyorthoesters, polyphosphate esters and polyanhydrides, and combinations of 5 these homopolymers, optionally PEGylated.
16. The method as claimed in any preceding claim, wherein the polymer is a copolymer selected from different poly(D,L-lactide-co-glycolide) polymers or other biodegradable or biocompatible copolymers.
- 10 17. The method as claimed in any preceding claim, wherein the volatile solvent is partially miscible or insoluble with water.
18. Use of a material obtained by the method as claimed in any preceding 15 claim, in implantable, depositable and or injectable delivery systems for sustained delivery of therapeutic active ingredients.
19. Use of a material obtained by the method as claimed in any of claims 1- 17, for functional food applications.
- 20 20. Use of particles obtained by the method as claimed in any of claims 1 -14, for making a formulation for inhalation or oral delivery of therapeutic active substances.
- 25 21. Composite material, comprising a polymer matrix exhibiting at least one domain comprising liquid crystalline phase or monolayer phase, said domain is dispersed within or on the surface of the matrix.
22. Material as claimed in claim 21, wherein said domains have a 30 micellar or vesicular structure containing at least one of second solvents, said structures being located within voids inside said polymer matrix.
23. Material as claimed in claim 21 or 22, in the form of particles.

24. Material as claimed in claim 21 or 22, in the form of solid implants, semi-solid, gel-like matrices, or surface coatings.

25. A vehicle for drugs for sustained or delayed release thereof, comprising a
5 material as claimed in any of claims 21-24.

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